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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,543	03/01/2004	Thomas Cavanak	100-6403R	9687
1095	7590	08/10/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,543

Applicant(s)

CAVANAK ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,10-14,16,18-35,37-42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,27,29-35 and 37 is/are rejected.
- 7) ☒ Claim(s) 3,5-7,10-14,16,18-26,28,38-42 and 44-48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 07/481,082.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20050711.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

S. O. D.

Art Unit: 1654

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2005 has been entered.
2. Claim 2 as set forth in the listing of claims filed July 11, 2005 is in improper format because its status identifier indicates that it is a previously presented claim even though the words "for oral administration" are underlined in the claim. In claims with the status "previously presented", no amendment markings should be present. See 37 CFR 1.121(c)(3). In claim 30, line 4 of the claim deletes a word, "dioctylsuccinate", which was not present in the previous version of the claim, and line 5 of the claim underlines a word, "dicotylsuccinate", which was present in the previous version of the word.
3. Claim 30 is objected to because of the following informalities: At claim 30, lines 3 (both occurrences) and 4, "polyoxyethylene" is misspelled. At claim 30, line 5, "dioctylsuccinate" is misspelled. Appropriate correction is required.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent No. 6,262,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '022 patent anticipate the instant claims. Note that an intended use limitation does not impart patentability to product claims where the product is otherwise taught by the reference. In any event, the capsule form recited in claim 12 of the '022 patent is a form suitable for oral administration.

6. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,652,212. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '212 patent anticipate the instant claim.

7. Claims 1, 27, 29-35, and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-18 and 20-22 of U.S. Patent No. 5,639,724. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '724 patent anticipate instant claims 1, 27, 30, 32, 33, and 35. With respect to instant claims 29, 31, 34, and 37, while the '724 patent does not claim the concentrations and proportions recited in the instant claims, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal concentrations and proportions for the claimed compositions of the '724 patent because concentration and proportion are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical composition arts.

Art Unit: 1654

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,916,589. The '589 patent teaches, in Examples 1.6 - 1.8, cyclosporin-containing compositions comprising Miglyol 812 (which comprises fatty acid triglycerides) and glycerol monooleate (which is a glycerol fatty acid partial ester). In addition, the '589 patent teaches propylene glycol mono- and di-esters as useful components of the cyclosporin-containing compositions. See columns 10-11, section 3.1.8, and

10. Applicant's arguments filed July 11, 2005 have been fully considered but they are not persuasive.

Applicants did not traverse the obviousness-type double patenting rejections remaining from the final Office action and repeated above.

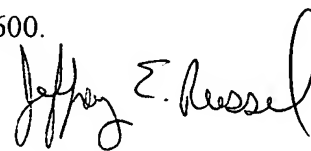
The anticipation rejection of claim 1 over U.S. Patent No. 5,916,589 is maintained. While glycerol fatty acid partial esters have been deleted from claim 1, part c), the '589 patent teaches another of the listed components, propylene glycol complete and partial esters. See section 3.1.8 of the '589 patent.

11. Claims 3, 5-7, 10-14, 16, 18-26, 28, 38-42, and 44-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1654

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looping "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

August 5, 2005